

### **DETAILED ACTION**

The receipt is acknowledged of applicants' amendment filed 09/29/2009.

Claims 1-3, 6, 7, 13-18, and 20 have been canceled. Claims 36-50 have been added by the amendment filed 09/29/2009.

Claims 4, 5, 8-12, 19, 21-50 are pending.

Claims 19, 21-33 are withdrawn from further consideration as being directed to non-elected invention.

Claims 4, 5, 8-12, 34-50 are included in the prosecution.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5, 34-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for benzoyl peroxide (BPO) particles of less than 50 microns as claimed by claim 4, does not reasonably provide enablement for any other

active ingredient having particle size between 10-150 microns as claimed by claim 5, up to 300 microns as claimed by claim 34 or less than 50 microns as claimed by claim 35. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

**The nature of the invention:** The nature of the invention is a drug delivery system comprising a container; and a liquid composition, wherein the composition comprises: (1) an effective amount of one or more insoluble dermatologically active ingredients, and (2) an emulsion vehicle for the dermatologically active ingredients, wherein the composition has a viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container, and wherein the active ingredient

comprises particles having sizes of between 10-150 microns (claim 5), up to about 300 microns (claim 34) or less than about 50 microns (claim 35).

**The breadth of the claims:** The claims are very broad. The claims encompass a wide classes and subclasses of active agents that have wide range of particle sizes.

**The state of the prior art:** The state of the art does not recognize BPO having particles size less than 50 microns. However, the art recognized active ingredients such as moisturizing agent having particle size between 0.2-200 microns as taught by US '766 by Sine et al., col.4, lines 23-29.

**The relative skill of those in the art:** The relative skill of those in the art is high.

**The amount of direction or guidance presented:** The specification provides no guidance, in the way written description, on active agents having the claimed particle sizes other than BPO. In page 5, paragraph 23 of the present specification applicant disclosed BPO having particle size less than 50 microns. Examples teach BPO. It is not obvious from the disclosure of BPO of specific particle sizes if the other active ingredients will work effectively in the instant delivery system. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope

of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

**The predictability or unpredictability of the art:** The lack of guidance from the specification with regard to reasonable number of active agents having the claimed particle sizes makes practicing the claimed invention unpredictable in the terms of active agent having the claimed particle sizes. The prior art teaches droplet size of moisturizing agent having the claimed particle sizes between 0.2-200 microns.

**The presence or absence of working examples:** The specification discloses only BPO having particle sizes less than 50 microns. No working examples to show other active agent having other particle sizes, e.g. over 50 microns.

**The quantity of experimentation necessary:** The art demonstrates moisturizing agent having particle sizes between 0.2-200 microns, and the specification taught BPO having particle sizes below 50 microns. Therefore, the practitioner would turn to trial and error experimentation to practice the instant composition comprising active agent having particle sizes of between 10-150 microns (claim 5), up to about 300 microns (claim 34) or less than 50 microns (claim 35). Therefore, undue experimentation becomes the burden of the practitioner.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 5, 8-12, 34-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "substantially uniformly" in claims 4, 5, 34 and 35 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the term does not set forth the metes and the bounds of the claims because the specification does not define the term.

6. The expression "less than about 50 microns" as claimed by claims 4 and 35 is indefinite because the term "less than" requires sizes below 50 microns only. To the contrary, the term "about" permits sizes above 50 microns.

7. The expression "up to about 300 microns" as claimed by claim 34 is indefinite because the term "up to" requires sizes below 300 microns only. To the contrary, the term "about" permits sizes above 300 microns.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/  
Primary Examiner, Art Unit 1611

IG